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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,362	01/08/2004	James Weldon	29985/03-006	7606

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EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/754,362	WELDON ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *24-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments filed on 2/22/2007. The Information Disclosure Statement filed on 2/13/2007 has been received. The Drawings received on 11/17/2006 have been accepted.

Election/Restrictions

Applicant's election without traverse of Group I claims 1-23 and 44-46 in the reply filed on 2/22/2007 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim recites, "an implantable device having no outwardly biasing structure associated therewith." The Examiner found no support for this limitation. Paragraph 32 of the specification suggests that the graft has some outwardly biasing structure because upon removal of

the wrapper, the end 83 opens. Figures 5 and 6A also suggest that the graft has some outwardly biasing structure. Also, the lack of an additional stent with the graft is not the same scope as the claimed limitation. The claim suggests that there is no structure whatsoever that may bias the graft in the outward direction. The material of the graft is not specifically stated as having no outwardly biasing structure. One having ordinary skill in the art would not assume that the graft necessarily lacks outwardly biasing structure. The scope of this claim is beyond the original disclosure and is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 22, 23, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Strecker (US 6,416,522).

Strecker discloses:

1. A fixation system for fixing an implantable device in a body cavity, comprising: an implantable device having no outwardly biasing structure associated therewith (80, 87); a plurality of resilient delivery members movable between a generally longitudinal delivery position and a radially expanded deployment position (93), the delivery

members defining a delivery channel therein with a distal opening, each delivery member having a distal end formed with a blunt profile adapted to engage the implantable device (Fig 12); a fixation component slidably disposed in each of the delivery channels (95); and a pusher slidably disposed in each of the delivery channels to push the fixation component in each delivery channel (98).

2. The fixation system of claim 1 and further comprising: a delivery sheath slidable over the plurality of resilient delivery members (89).

3. The fixation system of claim 1 wherein the delivery members define the delivery channel as a closed lumen therein with the distal opening (Fig 12).

22. The fixation system of claim 1 wherein the body cavity comprises a vascular lumen in a region of an aneurysm (intended use of device, no additional structure).

23. The fixation system of claim 1 wherein the delivery members are configured to exert outwardly directed pressure on an inner wall of the implantable device at substantially uniformly spaced areas, when in the deployed position (Fig 12).

44. A fixation system for use in a wall of a blood vessel having an aneurysm, comprising: a vascular graft sized (87) to extend across the aneurysm and having no outwardly biasing structure associated therewith; an array of delivery tubes (93)

advancable through a center lumen of the graft, each delivery member having a distal end formed with a blunt profile (93), the array of tubes being movable between a radially contracted position and a deployment position in which the distal ends of the delivery tubes expand radially to urge the graft against the wall (Fig 12); and a plurality of fixation components (95), one component slidably disposed in each delivery tube (Fig 12), the fixation components slidable out of the delivery tubes to connect the graft to the wall of the blood vessel (Fig 12).

45. The fixation system of claim 44 and further comprising: a plurality of plungers (98), one plunger slidably disposed in each delivery tube to advance the fixation components out of the delivery tubes (Fig 12).

46. The fixation system of claim 44 and further comprising: a delivery sheath (88) slidable over the array of delivery tubes, the delivery sheath holding the delivery tubes in the contracted position and removal of the delivery sheath allowing movement of the delivery tubes into the deployment position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (US 6,416,522) in view of Hlavka et al. (US 2004/0172046).

Strecker discloses the invention substantially as claimed as stated above. Strecker further discloses:

5. The fixation system of claim 4 wherein the delivery members, when in the deployed position, urge the implantable device against a wall of the body cavity (Fig 13).

6. The fixation system of claim 5 wherein the first fixation member is disposed to pierce the implantable device and a wall of the body cavity when advanced from the delivery channel by the pusher (Fig 13).

7. The fixation system of claim 6 wherein the first fixation member has a sharpened end for piercing the implantable device and body cavity wall (95).

8. The fixation system of claim 6 wherein the first and second fixation members are arranged in a generally longitudinally aligned orientation when in the delivery channel (Fig 14).

9. The fixation system of claim 8 wherein one of the first and second fixation members are releasably connected to the pusher (Fig 12).

Strecker does not disclose each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members.

Hlavka teaches each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members (Fig 10a Items 904 and 905). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Hlavka's fixation member and tether. Such a modification would allow the two members to be pulled against one another with the tissue and/or graft between them, thus securing the graft to the tissue.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (US 6,416,522) in view of Miller (WO 02/17797).

Strecker discloses the invention substantially as claimed as stated above.

Strecker does not disclose an inner sheath, a releasable fixation member, and an expandable member at the distal end of the sheath. Miller teaches an inner sheath, the plurality of delivery members being arranged generally radially about the inner sheath (Fig 12 Item 220), a releasable fixation member releasably fixing the vascular graft to a distal end of the inner sheath (Fig 16 Item 235), an expandable member expandable from a contracted position closely proximate an exterior of the delivery sheath to an expanded position urging the vascular graft against the wall of the body cavity (Fig 15 Item 210), the expandable member is positioned at a distal end of the delivery sheath

(Fig 10 Item 210), and the expandable member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery members in the deployment position (210). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Miller's inner sheath and expandable member. Such a modification would restrain the delivery members until deployment, fix the graft until deployment preventing undesirable release, and a balloon to ensure full expansion of the graft.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (US 6,416,522) in view of Starksen et al. (US 2004/0193191).

Strecker discloses the invention substantially as claimed as stated above.

Strecker does not disclose each of the delivery members defines an associated delivery channel as a channel having a slot communicating with an exterior of the delivery member; the fixation component comprises: a piercing member with a tether attached thereto; pairs of piercing members in adjacent delivery members are tethered together by the tether; the tether is oriented to ride through the slots in the adjacent delivery members as the pushers advance the piercing members through the channel in the delivery members; the pairs of piercing members are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity.

Starksen teaches each of the delivery members defines an associated delivery channel as a channel having a slot communicating with an exterior of the delivery member (Fig 9A Item 528); the fixation component comprises: a piercing member with a tether attached thereto (Fig 9B Item 534); pairs of piercing members in adjacent delivery members are tethered together by the tether (Fig 9B Item 534); the tether is oriented to ride through the slots in the adjacent delivery members as the pushers advance the piercing members through the channel in the delivery members (Fig 9B Item 534); the pairs of piercing members are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity (the Examiner considers "are advanced through the implantable device and through a wall of the body cavity, the piercing members pulling ends of the tether through the implantable device and through the wall of the body cavity" to be functional language directed at an intended use and therefore gives the clause no weight; Fig 9A Item 526 are directed at the piercing members). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's delivery members to include Starksen's slot and tether. Such a modification would provide a means to tighten the anchors for securing the graft against the vessel wall.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strecker (US 6,416,522) in view of Ginn (US 6,645,205).

Strecker discloses the invention substantially as claimed as stated above.

Strecker does not disclose a radio frequency (RF) energy source connected to the pushers to apply RF energy to a wall of the body cavity through the pushers and the fixation components.

Ginn teaches a radio frequency (RF) energy source connected to a device to apply RF energy to a wall of the body cavity through the device (Fig 12). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Ginn's RF source. Such a modification would allow the system to apply RF energy to the tissue. One may want to apply RF to fuse tissue.

Response to Arguments

Applicant's arguments with respect to claims 1-23 and 44-46 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has argued that Miller does not disclose a graft without outwardly biasing structure. The Examiner has removed the Miller USC 102 rejection and used Strecker to reject the claims as stated above. The Strecker patent discloses a graft with no additional structure for outwardly biasing the graft. The Examiner considers the rejection above to anticipate the claims or render them obvious. No additional arguments were made against the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

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SUPERVISORY PATENT EXAMINER
4/23/07